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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,657

02/25/2004

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ARB-9017.1

2854

23410

7590

06/26/2009

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

06/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,657	Applicant(s) WILLIAMSON ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,8,21-31 and 74-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, 8, 21-31 and 74-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Pyka et al. (5,002,563). Pyka et al. disclose, at least in figures 3-5B1 and in col. 5, line 8 to col. 6, line 2 and col. 7, lines 37-51; a method of placing a fastener (18) in a patient during surgery, where the method includes providing a fastener with formable portion and a base (33, 36, or bottom of the U-shape) and a leg (16) extending from the base, the leg having a point on one end and an indeterminate length measured from the base; locating fastener inside a patient on one side of tissue (24), driving a pointed end of the fastener through tissue using one leg, moving the fastener into position; grasping the leg after the leg has penetrated tissue, tensioning the leg (by pulling) and moving the base of the fastener against the tissue; immobilizing the leg on the other side of tissue (other side of a wound), and cutting the fastener between the base and the pointed end to form a new end on the leg, engaging or grasping the end of the immobilized leg (with “instruments”); and bending the leg (i.e., allowing the leg to bend) to force the end (28) back towards the base of the fastener.

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 27, 28, 74, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pyka et al. (5,002,563) in view of Conn (2,199,025). Pyka et al. disclose the invention substantially as claimed. Pyka et al. disclose, at least in figures 3-5B1 and in col. 5, line 8 to col. 6, line 2 and col. 7, lines 37-51; a fastener for use in surgery and a method, where the fastener and method include a body (18) having a base (e.g., 33 or 36) and a leg (16) extending from the base; the body having a width dimension; the leg having a pointed end (at 14), an unformed length dimension from the base to the pointed end, the length that is long enough to extend out of a patient when the base is in an anchoring position within the patient's body, the leg configured to be cut to a formed length dimension measured between said base and the pointed end with the end located between the pointed end and the base such that the unformed

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length is greater than the formed length, where the leg is formed from a material configured to be bent to force the new end back towards the base to secure the fastener to tissue (i.e., the leg is formed of a shape memory alloy that allows a new end to be bent back towards the base--see col. 5, lines 59-66). However, Pyka et al. do not disclose a pledget on the body adjacent to the base or placing a pledget or prosthesis on the fastener adjacent to the base or tissue. Conn teaches, at least in figures 2-4 and col. 3, lines 21-34; the placement of a pledget or prosthesis (14 or 17) adjacent to the base of a fastener (i.e., a portion of suture adjacent to the patient's skin) and adjacent to tissue 15. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Conn, to include a pledget or prosthesis with the fastener and method of Pyka et al. Such a pledget or prosthesis would not only protect tissue from trauma from the fastener body, it would allow absorption of secretions from a tissue wound and allow a means for delivery of therapeutic materials to the tissue.

5. Claims 5, 7, 8, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pyka et al. (5,002,563) in view of Levy (4,549,545). Pyka et al. disclose the invention substantially as claimed. Pyka et al. disclose a wire fastener with a U-shaped body having a base (bottom of the U-shape) and two legs (16, 26 or 38, 40 with respect to claim 76), the body having a width dimension measured from one leg to the other, one leg having a pointed end (at 14) and a length dimension measured from the base to the pointed end that is long enough to extend out of a patient when the base is in an anchoring position from the patient's body, where the body is formed from a material configured to be bent to force cut ends of the legs back towards the base to

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secure the fastener to tissue (i.e., the body is formed of a shape memory alloy that allows ends to be bent back towards the base--see col. 5, lines 59-66), where the U-shaped body includes an abrupt bend (at 28 and 30) between the base and each leg (38, 40). However, Pyka et al. do not disclose that the length dimension is greater than the width dimension by factors as claimed. Nevertheless, it would have been an obvious matter of design choice to size a leg as claimed, since such a modification would have involved a mere change in the size of component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Pyka et al. also do not disclose that another leg has a pointed end and a pledget adjacent the base. Levy teaches, at least in figure 1, a U-shaped fastener (14) with two pointed ends (12a, 12b) and a pledget (16) adjacent the base. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Levy, to include another pointed end and a pledget in the fastener of Pyka et al. Another pointed end would allow the convenient fastening of tissues from both ends of the fastener, while a pledget would protect tissues being fastened from trauma from the fastener body.

6. Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pyka et al. (5,002,563). Pyka et al. disclose the invention substantially as claimed, but do not specifically disclose grasping of tissue prior to driving the pointed end through tissue, placing a plurality of fasteners, and organizing the fasteners. Nevertheless, Pyka et al. also disclose, in col. 9, lines 13-15, an example of a wound repaired by a plurality of "sutures 10." Thus, it would have obvious to one having ordinary skill in the

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art at the time the invention was made to perform these steps. Grasping of tissue (manually or by “instruments” or by initial fasteners) would provide mechanical support to and positioning of soft tissues, so that a pointed end of a fastener may effectively penetrate tissue. The placing of a plurality of fasteners would allow the repair of a large wound or multiple wounds, while the organizing of fasteners would ensure that an adequate supply of fasteners is provided for a surgical procedure.

Response to Amendment

7. Applicant's arguments with respect to claims 1, 5, 7, 8, 21-31, and 74-76 have been considered but are not persuasive. That is, Pyka indeed discloses a fastener that includes a leg or body that is formed from a material configured to be bent to force an end of a leg towards the base to secure the fastener to tissue. Applicant is reminded that the recitation that an element is “configured to” perform a function only requires the ability to so perform. *In re Hutchison*, 69 USPQ 138. Pyka's fastener, which is made of shape memory material, has a leg or body capable of bending as claimed, where the bending forces are biasing forces from the shaped material. The claims do not require that the fastener undergo “plastic deformation” to achieve the bends as claimed. Applicant is further reminded that it is the claims that define the claimed invention, and it is the claims, not specifications or arguments, that are anticipated or unpatentable. *Constant v. Advanced Micro-devices Inc.*, 7 USPQ2d 1064.

With respect to arguments regarding the length dimension of each leg of the fastener: Although Pyka et al. may not disclose dimensions as claimed, choosing the size of a component, as claimed, is within the level of ordinary skill in the art. *In re*

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Rose, 105 USPQ 237 (CCPA 1955). Moreover, the claims do not require a suture size that would enable the guidance of a prosthesis or other device along the suture.

Finally, as mentioned in the rejection above, Pyka et al. indeed disclose a U-shaped body with an abrupt bend between the base and each leg, where the legs are deemed to be the tip portions, 38 and 40. Moreover, Pyka et al. recite a plurality of sutures (col. 9, lines 13-15)—a recitation suggesting the obviousness of placing and arranging (i.e., organizing) several sutures at a surgical site.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-

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4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773